510(k) SUMMARY

AUG - 1 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K102400

Submitted By: Diagnostics Direct, LLC
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Date Prepared: August 24, 2010

Trade or Proprietary Name: Syphilis Health Check

Common or Usual Name: Rapid immunochromatographic membrane assay, Treponema pallidum antibody.

Regulation 21 CFR 866.3830

Classification Class II (Special Controls)

Product Codes LIP

Panel: Immunology and Microbiology (83)

Predicate Device: K001552 - Phoenix Bio-Tech - TREPCHEK TREPONEMAL ANTIBODY EIA

Device Description SYPHILIS HEALTH CHECK is a rapid qualitative screening test for detection of human antibodies to TP in serum, plasma or whole blood.

The method employs an unique combination of anti-human immunoglobulins gold conjugate and highly purified TP recombinant proteins to specifically detect anti-TP antibodies. The test mainly detects IgG and IgM will also react in case of high concentrations.

As the samples flow through the absorbent device, the anti-human immunoglobulins/protein A dye conjugate binds to the human immunoglobulins forming an antigen-antibody complex. This complex binds to the recombinant protein in the positive reaction zone and produces a pink-rose colored band. In the absence of anti TP antibodies, there is no line in the positive reaction zone. The reaction mixture continues flowing through the absorbent device past the reaction and control zones. Unbound conjugate binds to the reagents in the control zone producing a pink-rose color band, demonstrating that the reagents are functioning correctly.

Intended Use Syphilis Health Check is a qualitative rapid membrane immunochromatographic assay for the detection of *Treponema pallidum* (syphilis) antibodies in human

whole blood, serum or plasma. This product can be used as an initial screening test or in conjunction with a non-treponemal laboratory test and clinical findings, may aid in the diagnosis of syphilis infection. This test is not intended for use in screening blood or plasma donors.

Indications for Use Syphilis Health Check is a qualitative rapid membrane immunochromatographic assay for the detection of *Treponema pallidum* (syphilis) antibodies in human whole blood, serum or plasma. This product can be used as an initial screening test or in conjunction with a non-treponemal laboratory test and clinical findings, may aid in the diagnosis of syphilis infection. This test is not intended for use in screening blood or plasma donors.

TECHNOLOGICAL CHARACTERISTICS

The following tables summarize similarities and differences between Syphilis Health Check and the current TREPCHEK Treponemal Antibody EIA (K001552):

ITEM	PREDICATE DEVICE	NEW DEVICE
Device name	**TREPCHEK**	**Syphilis Health Check**
Analyte	T. pallidum antibodies	T. pallidum Ig antibodies (Detection **of IgG and IgM** isotypes)
Specimens	Serum and plasma	**Whole Blood**, Serum, and Plasma
Method	Enzyme ImmunoAssay	**Rapid Immunochromato-graphic membrane**
Test principle	TREPCHEK is an enzyme-immunoassay utilizing specific recombinant treponemal antigens immobilized to microwells. Anti-treponemal specific antibodies in the patient's serum or plasma bind to the antigens. Non-bound proteins are removed during the washing step. Horseradish Peroxidase-labelled goat anti-human IgG is added to bind with the human antibodies in the well. The unbound conjugate is removed by a second washing step; then the chromogenic substrate TMB is added. After an appropriate incubation period, a stop solution is added and the absorbance of the resulting colour is measured photometrically with an EIA reader (450 nm). Colour intensity is proportional to the amount of specific antibody present in the patient's sample.	Specific, recombinant treponemal antigens are immobilized on the membrane. Patient samples or controls are added to the sample well, followed by a buffer, and as the sample flows through the absorbent device, the human immunoglobulins bind to the antigens forming an antigen-antibody complex. The antigen-antibody complex is further reacted with a unique combination of **colloidal gold conjugated** Protein A and anti-human immunoglobulins producing a pink-rose colored band that can be read visually indicating antibody is present in the patient's sample. A separate Control Line indicates reagents are functioning correctly

ITEM	PREDICATE DEVICE	NEW DEVICE
Antigen Used	Recombinant proteins	same
Detection	colorimetric detection - optical density	**Colloidal Gold - pink-red line visually read**
Calculation	Qualitative determination with ratiometric values Calibrator	**Qualitative determination from the Test Line**
Quality control	2 Controls at different levels	Positive and Negative Controls
Indication for use	Aid in the diagnosis of syphilis disease.	same
Sample Dilution	Diluted 100 µL per well	Undiluted **25 µL** or **50µL** per test well
Incubation Time	30 min / 30 min / 15 min	**10 - 15 min.**
Incubation Temperature	Room Temperature (18 - 25°C)	Room Temp (18 - 25°C)
Conjugate	Anti-human IgG – HRPO	**Protein A / Anti-human Ig – Colloidal gold**
Sensitivity	> 97%	>98%
Specificity	> 97%	>98%

Performance: The following are performance characteristics of Syphilis Health Check

In order to evaluate the performance of the Syphilis Health Check test as series of 880 patient samples were obtained that were from prospective study sites and 412 frozen retrospective samples purchased from outside commercial vendors and blood centers. In addition, a series of 164 clinically diagnosed samples were obtained that were known primary, secondary, and latent both treated and untreated. The total of **1292** known retrospective samples (576) and prospectively collected (880) patient samples were used to demonstrate the performance of the Syphilis Health Check test to Non-treponemal RPR and other treponemal tests.

Prospective Studies were conducted at five clinical study sites which compared the Syphilis Health Check to RPR, a non-treponemal test, and treponemal tests such as TPPA, TPHA, or ELISA, using specimens from patients coming into four STD clinics and one hospital clinic. The patients enrolled in the study were identified by medical associates as suspected positive for syphilis and exhibiting symptoms.

Initial evaluations were performed at a university clinic and a hospital clinic to assess the performance of the Syphilis Health-Check test versus RPR and their reference treponemal tests - FTA and TPHA. Only gender and age were collected from these patients. A more comprehensive study was performed at three study sites to collect further patient history information in order to identify a broader range of STD related patients. The information and data collected from these sites is presented below.

The Syphilis Health Check assay demonstrated 95.6% and 98.5% Percent Positive Agreement versus the non-treponemal test and treponemal tests respectively, and 90.5% and 97.3% Percent Negative Agreement respectively.

CUMULATIVE COMPARISON RESULTS

The results obtained for the prospective and retrospective samples yields the following results compared to Non-treponemal RPR and treponemal tests.

TOTAL Non-Treponemal Comparison - total combined sample results are presented from the 5 prospective sites and the frozen known and suspected positive samples.

		RPR - Non-Treponemal		
		Positive	Negative	Total
Syphilis Health Check	Positive	473	76	549
	Negative	22	721	743
	Total	495	797	1292

Percent Positive Agreement: 473/495 = 95.6% (95% C.I. = 93.4 - 97.2%)
Percent Negative Agreement: 721/797 = 90.5% (95% C.I. = 88.2 - 92.4%)
Percent Overall Agreement: 1194/1292 = 92.4% (95% C.I. = 90.8 - 93.8%)

TOTAL Treponemal Comparison - total combined sample results are presented from the 5 sites and the frozen known and suspected positive samples

		Reference Treponemal tests		
		Positive	Negative	Total
Syphilis Health Check	Positive	531	20	551
	Negative	8	733	741
	Total	539	753	1292

Percent Positive Agreement: 531/539 = 98.5% (95% C.I. = 997.1 - 99.4%)
Percent Negative Agreement: 733/753 = 97.3% (95% C.I. = 95.9 - 98.4%)
Percent Overall Agreement: 1264/1292 = 97.8% (95% C.I. = 96.9 - 98.6%)

PROSPECTIVE STUDIES

University Clinic site

		RPR		
		pos	neg	Total
Syphilis Health Check	pos	32	1	33
	neg	0	6	6
	Total	32	7	39

FTA		
pos	neg	Total
27	6	33
0	6	6
27	12	39

Percent Positive Agreement = 100.0% (95% C.I. = 89.1 - 100%) 100% (95% C.I. = 87.2 - 100%)
Percent Negative Agreement = 85.7% (95% C.I. = 42.1 - 99.6%) 50.0% (95% C.I. = 21.1 - 78.9%)
Percent Overall Agreement = 97.4% (95% C.I. = 86.5 - 99.9%) 84.6% (95% C.I. = 69.5 - 94.1%)

Hospital Clinic site

		RPR		
		pos	neg	Total
Syphilis Health Check	pos	3	3	6
	neg	0	44	44
	Total	3	47	50

TPHA		
pos	neg	Total
6	0	6
0	44	44
6	44	50

Percent Positive Agreement = 100.0% (95% C.I. = 29.2 - 100%) 100.0% (95% C.I. = 54.1 - 100%)
Percent Negative Agreement = 93.6% (95% C.I. = 82.5 - 98.7%) 100.0% (95% C.I. = 92.0 - 100%)
Percent Overall Agreement = 94.0% (95% C.I. = 83.5 - 98.7%) 100.0% (95% C.I. = 92.9 - 100%)

Study Site 1

		RPR		
		pos	neg	Total
Syphilis Health Check	pos	13	15	28
	neg	2	370	372
	Total	15	385	400

TPPA		
pos	neg	Total
21	8	29
6	365	371
27	373	400

Percent Positive Agreement = 86.7% (95% C.I.= 59.5 - 98.3) 77.8% (95% C.I.= 57.7 - 91.4)
Percent Negative Agreement = 96.1% (95% C.I.= 93.7 - 97.8) 97.9%(95% C.I.= 95.8 - 99.1)
Percent Overall Agreement = 95.8% (95% C.I.= 93.3 - 97.5) 96.5% (95% C.I.= 94.2 - 98.1)

It should be noted that two (2) of the false negative samples vs TPPA were only positive for TPPA but negative with the other two reference methods (RPR and FTA). Three samples were positive for TPPA and FTA, but negative for Syphilis Health Check and RPR.

Study Site 2

		RPR		
		pos	neg	Total
Syphilis Health Check	pos	2	2	4
	neg	0	85	85
	Total	2	87	89

TPPA		
pos	neg	Total
4	0	4
0	85	85
4	85	89

Percent Positive Agreement = 100.0% (95% C.I. = 15.8 - 100) 100.0% (95% C.I. = 39.8 - 100%)
Percent Negative Agreement = 97.7% (95%C.I. = 91.9 - 99.7) 100.0% (95% C.I. = 95.8 - 100%)
Percent Overall Agreement = 97.8% (95% C.I. = 92.1 - 100) 100.0% (95% C.I. = 95.9 - 100%)

Study Site 3

		RPR		
		pos	neg	Total
Syphilis Health Check	pos	6	4	10
	neg	0	195	195
	Total	6	199	205

EIA		
pos	neg	Total
9	2	11
1	193	194
10	195	205

P P A = 100.0% (95% C.I.= 54.1 - 100) 90.0% (95% C.I.= 55.5 - 99.7%)
P N A = 98.0% (95% C.I.= 94.9 - 99.4) 99.0% (95% C.I.= 96.3 - 99.9%)
P O A = 98.0% (95% C.I.= 95.1 - 99.5) 98.5% (95% C.I.= 95.8 - 99.7%)

RETROSPECTIVE STUDIES

Suspected and Known Positive Syphilis Samples

A series of 412 total samples were purchased from serum and blood center suppliers consisting of 149 banked RPR and treponemal reactive serum samples and 28 serum samples that were requested to be Primary or Secondary Patients, treated or untreated, but exhibiting a Syphilitic-type lesion or rash were purchased from a serum supplier, and 138 frozen serum and plasma samples were obtained from a blood center. The samples were found to be RPR and treponemal reactive and having mixed titers. Another series of 97 samples being highly suspected of having a syphilis infection were obtained from a serum supplier that were obtained from various laboratories around the U.S., and were submitted to the laboratories for testing. The samples were tested by RPR, TPPA, and MHA-TP as reference methods for comparison to Syphilis Health Check test.

The samples were further tested by an outside laboratory for TPPA titer and Syphilis Health Check results. 19 samples were found to be Negative for TPPA and Syphilis Health Check and Reactive RPR, four samples were negative by TPPA, but Positive by Syphilis Health Check and RPR, one sample was Syphilis Health Check negative and positive RPR and TPPA, and one sample was RPR neg but TPPA and Syphilis Health Check positive. The remaining two hundred eighty-nine samples remained Positive by all four methods. In the Suspected Positive patients two samples were negative with Syphilis Health Check, with one sample low reactive with RPR, and both samples Non-Reactive with TPHA. The results of the testing are shown below.

Known Positives

		RPR		
		pos	neg	Total
Syphilis Health Check	pos	293	1	294
	neg	20	1	21
	Total	313	2	315

TPPA		
pos	neg	Total
290	4	294
1	20	21
291	24	315

Percent Positive Agreement = 93.4% (95%C.I. = 89.8 - 96.0%) 99.6% (95%C.I.= 97.9 - 100.0%)
Percent Negative Agreement = 100.0% (95%C.I. = 100%) 85.7% (95%C.I.= 63.7 - 97.0%)
Percent Overall Agreement = 93.4% (95%C.I. = 89.8 - 96.0%) 98.6% (95%C.I.= 96.5 - 99.6%)

Suspected Positive

		RPR		
		pos	neg	Total
Syphilis Health Check	pos	62	25	87
	neg	0	10	10
	Total	62	35	97

TPHA		
pos	neg	Total
87	0	87
0	10	10
87	10	97

MHTP		
pos	neg	Total
87	0	87
0	10	10
87	10	97

PPA = 100.0% (95% C.I. = 94.2 - 100%) 100.0% (95% C.I. = 95.8 - 100%) 100.0% (95% C.I. = 95.8 - 100%)
PNA = 28.6% (95% C.I. = 14.6 - 46.3%) 100.0% (95% C.I. = 69.2 - 100%) 100.0% (95% C.I. = 69.2 - 100%)
POA = 74.2% (95% C.I. = 64.3 - 82.6%) 100.0% (95% C.I. = 96.3 - 100%) 100.0% (95% C.I. = 96.3 - 100%)

Clinically Diagnosed

A panel of one hundred sixty-four (164) well-characterized clinically diagnosed serum samples from treated and untreated patients with primary, secondary, and latent syphilis infections were obtained from a clinic serving a population of individuals with a variety of infectious diseases. The samples were tested with reference assay tests for RPR, TPPA, and FTA-ABS. The samples were then tested with Syphilis Health Check and the results are summarized below.

Known Clinical Status		RPR	TPPA	FTA-ABS	Syphilis Health Check	No.	% Agree-ment	95% C.I.
Untreated	Primary	React	React	React	React	23	100	85.2 - 100%
	Seconda ry	React	React	React	React	25	100	86.3 - 100%
	Latent	React	React	React	React	22	100	84.6 - 100%
		NR	React	React	React	3	100	29.2 - 100%
Treated	Primary	React	React	React	React	28	100	87.8 - 100%
	Seconda ry	React	React	React	React	26	100	86.8 - 100%
	Latent	React	React	React	React	18	100	81.5 - 100%
		NR	React	React	React	19	100	82.4 - 100%
					Total	164	100	97.8 - 100%

Interference Study

Interference testing was conducted using serum. Concentrates of the compounds were prepared and diluted to multiple concentrations into eight sera with different levels of syphilis reactivity. The following results were obtained:

Hemoglobin: No effect was observed up to 1000 mg/dL of hemoglobin;

Bilirubin (total): No effect was observed up to 40 mg/dL of total bilirubin;

Triglycerides: No effect was observed up to 3000 mg/dL of triglycerides.

Cholesterol (total): No effect was observed up to 400mg/dL of cholesterol

Albumin: No effect was observed up to 1000 mg/dL of albumin

Gamma-globulin: No effect as observed up to 5000 mg/dL of gamma-globulin

Potential Cross Reactors:

Panels of samples were obtained to evaluate potential interference from different disease conditions confirmed positive and containing different concentrations of potentially cross-reactive antibodies and were analyzed with the Syphilis Health Check test. From 151 (138 Males) prospectively collected drug users eleven (7%) were found syphilis positive by reference methods and Syphilis Health Check, with two additional samples found positive for Syphilis Health Check. Two samples from Lyme disease and HSV showed a positive result with Syphilis Health Check but could not be confirmed. One sample each from CMV positive and heterophile positive patients were found Syphilis Health Check positive, but non-reactive by reference methods . Two HPV patients were found Syphilis Health Check positive with one confirmed by reference methods. Two co-infected Chlamydia/GC patients were found Syphilis Health Check and one confirmed positive by TPPA. The number of disease condition categories and reactive results obtained is listed in the following table.

Cross-reactor	Number	# positive by Syphilis Health Check	# positive by reference method(s)
Self-reported Drug Users	151	13	11
ANA Positive	24	0	
RF Positive	40	0	
U.S. Lyme Disease IgG & IgM	25	1	Not confirmed
HSV	24	1	Not confirmed
CMV	10	2	1
EBV	21	0	
HAV	25	0	

HIV 1 & 2	14	1	1
HTLV	14	1	1
Heterophile	32	1	0
HCV	24	1	1
Anti-HBs	25	2	2
Other STD - GC, Chlamydia, HPV, Trichomonas,	78	4	2

Syphilis Positive HIV / HCV / HBV Patients

A series of 13 patient EDTA Plasma samples from a blood center were identified that were screened RPR positive in patients that were also confirmed positive for HIV, HCV and/or Hepatitis B virus. Three of these patients were further identified as previously testing positive for syphilis and treated at that time. All of the samples were tested with TPPA and Syphilis Health Check to evaluate syphilis reactivity. All 13 samples were positive for RPR, TPPA, and Syphilis Health Check.

To further evaluate the influence of HIV on Syphilis Health Check results, a series of 24 banked serum containing high levels of viral load for HIV were tested with Syphilis Health Check. The HIV positive patient samples were purchased from a commercial serum supplier that were known to be RPR and/or Treponema positive. The samples were tested by an outside lab with the Syphilis Health Check test to assess reactivity. Six of these samples were Nonreactive by RPR but reactive with TPHA. One sample was RPR positive, but TPHA nonreactive. All 24 samples were Syphilis Health Check Positive.

Pregnant Women

A series of sixty-nine (69) pregnant female samples were purchased from a vendor that had known trimester, age, and ethnicity. An additional set of 93 pregnant women serum samples were obtained from a commercial source that were identified as syphilis positive by RPR screening and further tested with TPPA and Syphilis Health Check. Age and trimester were known, but ethnicity was not identified. Three samples out of the 162 total samples were RPR low positive but nonreactive by the treponemal methods.

Pregnant Women

Summary

		RPR		
		pos	neg	Total
Syphilis Health Check	pos	91	0	91
	neg	3	68	71
	Total	94	68	162

TPPA		
pos	neg	Total
94	0	94
0	68	68
94	68	162

Percent Positive Agreement =	96.8% (95% C.I.= 91.0 - 99.3%)	100.0% (95% C.I.= 96.2 - 100%)
Percent Negative Agreement =	100.0% (95% C.I.= 94.7 - 100%)	100.0% (95% C.I.= 94.7 - 100%)
Percent Overall Agreement =	98.1% (95% C.I.= 94.7 - 99.6%)	100.0% (95% C.I.= 97.7 - 100%)

PRECISION and REPRODUCIBILITY

Studies were performed to demonstrate the Intra-Assay, Inter-day, and Inter-Lot reproducibility of the Syphilis Health Check Test kit.

To demonstrate the reproducibility of the Syphilis Health Check test three laboratory sites using two trained technicians at each site to perform the testing for within-Run and between day reproducibility using a panel of 6 pooled samples. Each testing site conducted reproducibility studies using a supplied panel ranging from non-reactive to highly reactive, i.e. one nonreactive, one borderline, one borderline reactive, one moderate reactive, and two mid-high to high reactive in addition to the kit controls. Each site ran these panel member solutions for at least 5 days, twice per day. Each site performed one Within-Run assay by each of the operators each run for 10 times on one day. The one negative and three low to high positive samples had 100% agreement. The two borderline samples near the cut-off yielded the following results.

The following summary demonstrates the Reproducibility of the two critical borderline samples obtained by the Technicians.

Intra-Run

Panel D (Borderline Reactive)

	Positive	Negative	Expected	% Agree	Discrepant
Site 1 (2 operators)	57	3	60 positive	95.0	3
Site 2 (2 operators)	58	2	60 positive	96.7	2
In-house (2 operators)	59	1	60 positive	98.3	1

Panel E (Borderline Nonreactive)

	Positive	Negative	Expected	% Agree	Discrepant
Site 1	1	59	60 negative	98.3	1
Site 2	2	58	60 negative	96.7	2
In-House	0	60	60 negative	100.0	0

Inter-Day (5 days)

Panel D (Borderline Reactive)

	Positive	Negative	Expected	% Agree	Discrepant
Site 1 (2 operators)	57	3	60 positive	95.0	3
Site 2 (2 operators)	58	2	60 positive	96.7	2
In-house (2 operators)	57	3	60 positive	95.0	3

Panel E (Borderline Nonreactive)

	Positive	Negative	Expected	% Agree	Discrepant
Site 1	2	58	60 negative	96.7	2
Site 2	2	58	60 negative	96.7	2
In-House	1	59	60 negative	98.3	1

Inter-Lot

Studies were performed to demonstrate the Inter-Lot assay reproducibility of the Syphilis Health Check Test kits. The Inter-Lot study used four dilutions of a positive pool and negative sera samples. These five samples were run in duplicate on 5 different lots to demonstrate lot-to-lot reproducibility run on the same day by the same technician.

The following table demonstrates the reproducibility of the Syphilis Health Check Test over 5 lots of kits.

Dilution	Results after 10 min.					
	Expected results	**Lot I**	**Lot II**	**Lot III**	**Lot IV**	**Lot V**
Negative serum	-	-	-	-	-	-
$1/10^4$	-	-	-	-	-	-
$1/10^3$	+/-	+/-	+/-	+/-	+/-	+/-
$1/10^2$	+	+	+	+	+	+
1/10	+	+	+	+	+	+

EXPECTED VALUES

To assess the normal range (Expected Values) of the Syphilis Health Check test a series of ninety-eight (98) samples were obtained from various hospital laboratories in different U.S. geographical locations. The samples came from a general "presumed" healthy normal population (ages 20 – 66) whose serum or plasma were collected by hospital laboratories for routine serology testing, not related to STD.

All of the samples were tested with RPR, TPPA and Syphilis Health Check tests. Two samples were found positive by the treponemal tests with both samples non-reactive with RPR. These 2 samples were confirmed with MHA-TP.

The results of the testing of a presumed normal population obtained the following results for the Syphilis Health Check test: This resulted in a Overall Agreement of 100%. Therefore from this study of 98 presumed normal samples 2 were confirmed positive resulting in a 2% positivity rate.

In a prospectively collected population of drug users visiting STD clinics, of 138 males and 13 females (ages 18 - 61 yrs) thirteen (8.6%) were found to be Syphilis Health Check positive with eleven of those also reference method positive.

In a series of 69 pregnant women, ages 20 - 40 yrs, that were tested for routine screening, one sample (1.4%) was found to be Syphilis Health Check positive and confirmed by reference methods.

Eight hundred eighty (880) patients were prospectively collected in a population of individuals visiting STD and a hospital clinics and POC sites complaining and/or exhibiting signs and symptoms of STD infections, ages 16 - 81 yrs, and having 53% to 47% male to female ratio. It was found that a range of 3% - 6% of the patients identified as suspected syphilis were found positive by Syphilis Health Check and yielded a Percent positive agreement to RPR of 98.3% and 95.7% to treponemal tests. Percent Negative Agreement to RPR and Treponemal test was 93.4% and 97.8% respectively. Overall Agreement to RPR and Treponemal tests was 94.1% and 97.4% respectively.

These results are consistent with published rates for prevalence of antibody in the adult population. Prevalence may vary depending on a variety of factors such as geography, age, socio-economic status, ethnic background, type of test employed, specimen collection and handling procedures, clinical and epidemiological history.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993

Diagnostics Direct, LLC
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President
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AUG - 1 2011

Re: K102400
Trade/Device Name: Syphilis Health Check Treponemal Antibody Test; Rapid immunochromatographic membrane assay, *Treponema pallidum*
Regulation Number: 21 CFR 866.3830
Regulation Name: *Treponema pallidum* treponemal test reagents
Regulatory Class: Class II
Product Code: LIP
Dated: July 21, 2011
Received: July 27, 2011

Dear Mr. Lehnus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-

1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102400

Device Name: Syphilis Health Check Test

Indications For Use:

Syphilis Health Check is a qualitative rapid membrane immunochromatographic assay for the detection of *Treponema pallidum* (syphilis) antibodies in human whole blood, serum or plasma. This product can be used as an initial screening test or in conjunction with a non-treponemal laboratory test and clinical findings to aid in the diagnosis of syphilis infection. This test is not intended for use in screening blood or plasma donors.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K102400